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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/665,240

09/19/2003

Tommy Ekstrom

06275-188002

6971

26164 7590 05/05/2008

FISH & RICHARDSON P.C.

P.O BOX 1022

MINNEAPOLIS, MN 55440-1022

EXAMINER

CARTER, KENDRA D

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

05/05/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Art Unit: 1617

Continuation:

For purposes of appeal, the proposed amendments will be entered, but do not place the application in condition for allowance because of the reasons below. Thus, all rejection of claims 13-29, 34, 36 and 42-51 are upheld.

The Applicant argues that the obvious-double patenting rejection rejects claims that were cancelled and request for clarification of the precise claims being rejected. The Examiner acknowledges the error and clarifies that claims 13-15, 17, 19, 20, 22-25, 34, 36 and 42 are provisionally rejected on the ground of unstatutory double patenting over copending Application No. 09/367,950.

The Applicant further argues that the total daily dose taught by Carling is inextricably linked to the twice daily administration regime. There is no teaching in Carling that the patient should decide for himself when to increase or decrease the daily dosage. Regardless of the number of doses inhaled at each of the two daily administrations (i.e. morning or evening), the number of daily administrations does not change. The Examiner disagrees for the reasons given on pages 8, 9 and 21 of the previous office action.

The Applicant further argues that the Examiner's arguments of Exhibit 1 and 3-5 are not clear and provides a teaching-away from the present invention and not unexpected

results. The Examiner notes that the evidence provided in Exhibit 1 is not commensurate to scope with the claimed invention because the Exhibit 1 is administration of budesonide as the sole active ingredient, while the claimed invention is an admixture of budesonide and formoterol. In regards to Exhibit 3, the admixture is of fluticasone and sameterol xinafoage, which are two drugs not even claimed in the current application. In regards to Exhibit 4 and 5, the admixture is of budesonide, formoterol and terbutaline or budesonide and terbutaline, while the closest prior art is only the administration of the combination of budesonide and formoterol. In regards to further arguments in regards to Exhibit 5, the Examiner maintains the arguments given on pages 19 and 20.

The Applicant further argues that the Examiner's arguments is perfectly consistent with applicant's position that the patient can not administer the product on an as-need basis as determined by the patient. The Examiner disagrees for the reasons on pages 14 and of the previous office action. The entire argument should be considered by the applicant and not just the first part.

The Applicant further argues that Exhibit 4 and 5 are post-filing date publications and can not be used to one of ordinary skill prior to the present application's filing date. The Examiner agrees and has not used Exhibit 4 or 5 in the rejection, but to further support the Examiner's arguments in response to the Applicant's arguments.

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The Applicant further argues that surprising results should be considered in regards to Exhibits 4 and 5. The Examiner disagrees because Carling et al. teaches that the combination the combination of budesonide and formoterol have greater efficiency and duration of bronchodilator action, and rapid onset action, which provides rescue medicine, adequate dosing for treating asthma (see page 4, lines 4-21).